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Development and evaluation of the lifestyle intervention “Obeldicks light” for overweight children and adolescents

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This study is registered at clinicaltrials.gov (NCT00422916).

1Abstract

2Aim:

3Specific interventions for overweight but not obese children have not been established yet.
4Therefore we developed the methods, materials, and an evaluation protocol of a lifestyle
5intervention for overweight children based on an intervention for obese children.

6Subjects and Methods:

7The one-year lifestyle intervention “Obeldicks” for obese children comprised of
8physical activity, nutrition education, and behaviour counselling including an individual
9psychological care for both children and their parents was shortened reducing the amount
10of exercise training and individual counselling about 50% to a six-month intervention
11(“Obeldicks light”).

12Results:

13The evaluation protocol was based on guidelines and validated instruments with available
14German healthy normal-weight controls. As ideal study design a multi-centre randomized
15controlled trial with the primary outcome change of weight status was identified. As
16secondary outcomes improvement of body composition (skinfold thicknesses;
17bioimpedance analyses), cardiovascular risk factors (blood pressure; waist circumference),
18quality of life, dietary habits, eating, exercise, and sedentary behaviour were established.
19Potential influencing factors for treatment success were identified such as parental BMI,
20ethnicity, and socioeconomic status. All proposed instruments were validated in the
21German representative KiGGS and DONALD study.

22**Conclusions:** Adapting a well-established program for obese children to overweight
23children is an easy way to create a lifestyle intervention for overweight children. Our study
24protocol using instruments validated in German normal weight cohorts allows evaluating
25this new intervention.

26

27**Key words:** lifestyle intervention, overweight, children, adolescents, randomized-
28controlled-trial, evaluation

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31

32Introduction

33Overweight and obesity in childhood and adolescence is increasing world-wide (Ebbeling
34*et al.* 2002). Since overweight children tend to become obese adults and overweight affects
35both the children's health and their social integration (Ebbeling *et al.* 2002), effective
36treatments are needed. Overweight and its associated comorbidities such as hypertension,
37dyslipidemia, and disturbed glucose metabolism -which appear also frequently in children
38(l'Allemand *et al.* 2008;Reinehr *et al.* 2005a) - are likely associated with morbidity and
39premature death (Baker *et al.* 2007;Biro & Wien 2010). A large epidemiological study
40demonstrated the association between body-mass index (BMI) in childhood (7 through 13
41years of age) and coronary heart disease (CHD) in adulthood (25 years of age or older) in a
42cohort of >270,000 Danish (Baker *et al.* 2007).

43Guidelines recommend long-term outpatient training programs consisting of a combination
44of physical exercise, nutrition education, and behaviour counselling for obese children and
45adolescents, but only few programs have run and have been evaluated in the past (Oude *et*
46*al.* 2009;Monasta *et al.* 2010). A recent Cochrane review (Oude *et al.* 2009) concerning
47treatment in already obese children including 64 randomized controlled trials (RCTs) with
485,230 participants identified lifestyle interventions for obese children focused on physical
49activity and sedentary behavior in 12 studies, diet in 6 studies, and 36 concentrated on
50behaviorally orientated treatment programs. The studies included varied greatly in
51intervention design, outcome measurements and methodological quality. Meta-analysis
52indicated a reduction in weight at 6 and 12 months follow up in lifestyle interventions.
53While there is limited quality data to recommend one treatment program to be favored over
54another, this review shows that combined behavioral lifestyle interventions compared to
55standard care or self-help can produce a significant and clinically meaningful weight
56reduction in obese children and adolescents.

57However, all RCTs have focused on obese children so far and even less is known about
58intervention effects in overweight children (Monasta *et al.* 2010;Oude *et al.* 2009).
59Probably, similar positive effects as in obese children can be reached in overweight
60children with less treatment intensity. Furthermore, the findings from interventions in
61obese children cannot be directly transferred to overweight children, since degree of
62overweight may influence the outcome. For example, lower weight may be associated with
63lower awareness of weight problems or less treatment motivation.

64In this paper, we describe the development of a lifestyle intervention as well as the
65evaluation design to prove the effectiveness of this intervention in overweight children and
66adolescents.

67Subjects/Methods

68Development of the intervention “Obeldicks light”

69The lifestyle intervention for overweight children and adolescents (called “Obeldicks
70light”) was developed based on the experiences of the well-established “Obeldicks”
71intervention for obese children and adolescents. The name “Obeldicks” is adapted from the
72popular French obese comic figure “Obelix”. This figure was chosen since it is associated
73with positive qualities such as strength.

74Lifestyle intervention “Obeldicks”

75The complete material and the exact description of the one-year lifestyle intervention
76“Obeldicks” is available as a training book (Reinehr *et al.* 2010a). Briefly, this intervention
77is based on physical activity, nutrition education, and behaviour counselling including
78individual psychological care of the child and his/her family (see figure 1). Inclusion
79criteria are obesity (BMI > 97th percentile (Kromeyer-Hauschild K *et al.* 2001)), age 8 to
8016 years, apparently healthy and not on any medication, as well as attending regular
81school. An interdisciplinary team of paediatricians, diet-assistants, psychologists, and
82exercise physiologists is responsible for the training. Children older than 10 years are
83separated into gender-specific intervention groups, while younger boys and girls received
84the intervention together.

85The lifestyle intervention “Obeldicks” for obese children and adolescents led to a reduction
86of overweight in 70% of the more than 1000 participants and even four years after end of
87intervention the weight reduction was sustained (Reinehr *et al.* 2010b). Furthermore, the
88reduction of weight was associated with an improvement of cardiovascular risk factors
89such as hypertension, dyslipidemia, disturbed glucose metabolism, and metabolic
90syndrome not only at the end of intervention but also one year after end of intervention
91(Reinehr *et al.* 2006). Additionally, this lifestyle intervention led to a reduction of carotid
92intima-media thickness (Wunsch *et al.* 2006), a predictive factor for atherosclerosis, heart
93attack, and stroke (Lorenz *et al.* 2007). Finally, the weight loss was also associated with an
94improvement of quality of life in the participants suggesting a clinical relevance not only
95from the medical point of view but also from the participants’ point of view (Reinehr *et al.*
962005b). According to these promising results we decided to adopt this effective lifestyle

97intervention to overweight but not obese (BMI $>90^{\text{th}} < 97^{\text{th}}$ percentile (Kromeyer-Hauschild
98K *et al.* 2001)) children and called this new type of intervention “Obeldicks light”.

99

100Lifestyle intervention “Obeldicks light”

101Since the children were only overweight and not obese, the intervention was shortened
102from 1 year (“Obeldicks”) to 6 months (“Obeldicks light”). Compared to “Obeldicks”, the
103amount of physical activity training and the time- and cost-intensive individual counselling
104were reduced about 50%. We chose the same inclusion criteria as for “Obeldicks”. The
105differences between “Obeldicks” and “Obeldicks light” are demonstrated in figure 1. In
106“Obeldicks light”, the same training material as in “Obeldicks” (Reinehr *et al.* 2010a) are
107used.

108-please insert figure 1 here-

109Since in the lifestyle intervention “Obeldicks” the material in the nutrition and eating
110behaviour course as well as the sport games are age- and gender- specific for children > 10
111years (Reinehr *et al.* 2010a), children and adolescents older than 10 years are divided into
112groups according to their sex and age while younger boys and girls received the
113intervention together.

114The intervention team covers many disciplines and consists of paediatricians, diet-
115assistants, psychologists, and exercise physiologists trained in the methods of “Obeldicks”.
116All therapists have to build up a therapeutic alliance with the children and their families.
117They have to involve family members, adopt a non-blaming position, assume motivation,
118focus on small changes, identify the resources of the family, and create a positive climate
119by reframing (for details see (Flodmark 2005)).

120The exercise therapy takes place once a week throughout the whole 6 intervention months.
121Apart from this, the training program “Obeldicks light” is divided into two phases (see
122figure 1): In the intensive phase (3 months), the children take part in the nutritional course
123and in the eating-behaviour course in six group-sessions each lasting for 1.5 hours. At the
124same time, the parents are invited to attend six parents’ evenings each lasting 1.5 hours.
125Furthermore, a session of individual nutrition counselling is provided. In the establishing
126phase (three months), one further session of individual nutrition counselling and three
127individual counselling sessions for the child and his/her parents (30 minutes/month) are
128offered.

129The exercise therapy consists of trampoline jumping, jogging, ball games, dancing for
130girls, wrestling for boys, and instructions in physical activity as part of every-day life.
131Furthermore, reduction of the amount of time spent watching television or playing
132computer games is aimed by presenting alternative activity games, which can be played
133even with few friends without materials under all day circumstances.

134The nutritional teaching is based on the prevention concept of the “Optimized mixed diet”.
135In this concept evidence-based recommendations are translated into food-based dietary
136guidelines also considering the dietary habits of children and families in Germany. In
137contrast to the present-day diet of children in Germany with a fat-content of 38% of energy
138intake (E%), 13 E% proteins, and 49 E% carbohydrates including 14 E% sugar, the
139“Optimized mixed diet” is both fat and sugar reduced and contains 30 E% fat, 15 E%
140proteins, and 55 E% carbohydrates including 5 E% sugar (Reinehr *et al.* 2010a). The
141children follow a “traffic-light system” when selecting their food. In this system, the foods
142and drinks available in Germany are separated according to their fat and sugar contents
143into “red = stop”, “orange = consider the amount”, and “green = o.k. when hungry or
144thirsty”.

145The eating behaviour course is predominately behavioural-cognitive but also using
146systemic treatment approaches (Reinehr *et al.* 2010a): The training is based on behaviour
147contracts, booster systems, self reflecting curves, impulse control techniques, self
148instructions, cognitive restructuring, development of problem solving strategies, training of
149social competences, model learning via parents and prevention of relapses. One important
150aim of the eating behaviour course is to transfer rigid to flexible eating behaviour. The
151individual counselling sessions based on systemic and solution-focused theories are aimed
152to develop concrete solutions to change the family health behaviour consistently tailored to
153the individual family situation.

154The intervention “Obeldicks light” is offered in two cities (Marl and Datteln) in north-west
155Germany.

156**Evaluation of the intervention “Obeldicks light”**

157To prove the effectiveness of the lifestyle intervention “Obeldicks light” we developed an
158evaluation protocol based on the recommendations of German guidelines for obese
159children and adolescents (www.a-g-a.de/Leitlinie.pdf 2011) and reviews (Ebbeling *et al.*
1602002;Oude *et al.* 2009). We decided to perform a study with the best known evidence
161(Ebbeling *et al.* 2002;Oude *et al.* 2009), a randomized controlled multi-centre study to

162prove the effectiveness of the lifestyle intervention for overweight children. Using a
163computer generated randomization list the children were randomized into an intervention
164group (6 months intervention) or into a control group (waiting period of 6 months). The
165study was an open randomized controlled trial since blinding was not possible due to the
166nature of the intervention.

167The evaluation design is summarized in table 1. The primary goal was to reduce
168overweight and therefore change of weight status was the primary outcome. We decided to
169use the change of standard deviation BMI (BMI-SDS) as change of weight status since
170BMI is gender and age dependent in childhood. The degree of overweight was quantified
171using Cole's least mean square method, which normalized the BMI skewed distribution
172and expressed BMI as a standard deviation score (BMI-SDS) (Cole TJ 1990). Reference
173data recommended in guidelines for German children were used (Kromeyer-Hauschild K
174*et al.* 2001; www.a-g-a.de/Leitlinie.pdf 2011). For best available accurate measurements of
175BMI we measured height to the nearest centimetre using a rigid stadiometer and weight
176was measured unclothed to the nearest 0.1 kg using a calibrated balance scale.

177-**please insert table 1 here-**

178One of the secondary aims of the study was to describe the change of body composition.
179The gold standard to determine body composition is DEXA (www.a-g-a.de/Leitlinie.pdf
1802011). However, this measurement is based on X-ray. Therefore we decided to analyze
181body composition by indirect measurements which are well related to DEXA
182measurements (Haroun *et al.* 2009; Slaughter *et al.* 1998). We measured skinfold thickness
183by one investigator at baseline and in follow-up to account for the problem of interpersonal
184variability which is a relevant confounder of this measurement. To reduce intrapersonal
185variability triceps and subscapularis skinfold thickness was measured twice using a caliper
186and averaged. The percentage of body fat was calculated with validated formulas (boys:
187body fat % = $0.783 \times (\text{subscapularis skinfold thickness} + \text{triceps skinfold thickness in mm})$
188+1.6; girls: body fat % = $0.546 \times (\text{subscapularis skinfold thickness} + \text{triceps skinfold}$
189thickness in mm) +9.7) (Slaughter *et al.* 1998). Furthermore, an additional method of
190determining body composition was used to validate the body composition measurements
191(Haroun *et al.* 2009): Bioelectrical impedance was measured using leg-leg and hand-leg
192systems (BC418; TANITA, Uxbridge, UK). We used estimates of total body fat, lean body
193mass, and percentage body fat provided by the manufacturer's software based on age,
194gender, height, and weight. No information regarding the formulas used could be obtained
195from the manufacturer due to its commercially sensitive nature.

196From a medical point of view an improvement of cardiovascular risk factors is demanded
197in a lifestyle intervention for overweight children. The main cardiovascular risk factors of
198overweight are central adiposity, hypertension, dyslipidemia, and disturbed glucose
199metabolism in childhood (Ebbeling *et al.* 2002;www.a-g-a.de/Leitlinie.pdf 2011). Since a
200vein puncture is necessary for the determination of lipids and glucose metabolism, we
201decided to measure blood pressure and waist circumference for body fat distribution to
202keep the expenditure as low as possible for the children in the study. Blood pressure was
203measured by one investigator at baseline and in follow-up to account for the problem of
204interpersonal variability which is a relevant confounder of this measurement. After a 10-
205minute rest in the supine position systolic and diastolic blood pressure were measured by
206using a calibrated sphygmomanometer at the right arm according to current guidelines
207(2004) twice and averaged to reduce intrapersonal variability. Furthermore, we determined
208waist circumference, which is highly predictive for cardiovascular risk factors and is a
209measurement of central adiposity (www.a-g-a.de/Leitlinie.pdf 2011). Waist circumference
210was measured by one investigator to account for the problem of interpersonal variability.
211Again, to reduce intrapersonal variability waist circumference was measured twice and
212averaged.

213From the patient's point of view, improvement of quality of life represents the relevance of
214weight loss since overweight is associated with a reduced quality of life (Wille *et al.* 2008).
215We measured the quality of life by the parent and child version of the KINDL®
216questionnaire since all these questionnaires are validated and in use internationally and in
217Germany (Wille *et al.* 2008). Furthermore, a representative norm sample for Germany
218exists from the KiGGS study (Ravens-Sieberer *et al.* 2008). The KiGGS study is a German
219national representative study performed in the years 2003-2006 determining health status
220and health behaviour of children (Kurth *et al.* 2008). The KINDL® is a short generic
221instrument and measures the six dimensions physical well-being, emotional well-being,
222self-esteem, family, friends and everyday functioning (school) with a total of 24 items. The
223KINDL® adiposity specific disease module was additionally included in the parent's
224questionnaires as well as in adolescent's questionnaires.

225Understanding which parts of the interventions work and which fail will help to improve
226the lifestyle intervention. For this purpose the kinds of health behaviour was determined as
227secondary outcome, which are aimed to be changed by the lifestyle intervention.
228Therefore, we decided to measure dietary, eating, exercise, and sedentary behaviour.
229Three-day weighed dietary records were used for the evaluation of dietary intake, which

230are the best available accurate measurements (Kersting *et al.* 2005). Furthermore, a
231representative healthy German cohort was also measured by this method in the DONALD
232study (Sichert-Hellert *et al.* 2001). The DONALD study is an ongoing representative study
233analyzing the dietary habits of healthy German children (Sichert-Hellert *et al.* 2001).

234Eating behaviour was assessed by self-report in adolescents by an adapted version of the
235FEV questionnaire (Westenhoefer & Pudel 21989) which is a German version of the
236Three-Factor-Eating-Questionnaire (Stunkard & Messick 1985). We used this
237questionnaire since this instrument was evaluated in German children and is used in
238several studies regarding childhood obesity in Germany (Hoffmeister *et al.* 2010). Only the
239two dimensions dietary restraint and disinhibition were included. Additionally, we
240measured the habit strength of eating sweets as well as fruits and vegetables by the Self-
241Report Habit Index (SRHI) (Verplanken & Orbell 2003) since habit reflects more the
242stability of eating behaviour than the actual amount of consumed foods. To entrench
243positive eating habits on the long run is a central goal of nutrition interventions.

244Physical activity and sedentary time were measured by components from different
245instruments to obtain a comprehensive picture of these complex behaviours. Vigorous
246physical activity was determined by a semi-quantitative questionnaire evaluated in German
247children in the representative KIGGS study (Lampert *et al.* 2007a;Kurth *et al.* 2008). This
248questionnaire measures the frequency of vigorous physical activity not including school
249sport and exercise training as part of the intervention. The scales were 1=never, 2=once up
250to twice per month, 3=once up to twice per week, 4=three- up to five- times per week, 5=
251every day). Additionally parts of the Karlsruhe Activity questionnaire (KAF) (Bös *et al.*
2522010) were used to measure different every day activities (e.g. transportation to school).
253This questionnaire was also used in the representative KIGGS- study (Kurth *et al.* 2008).
254Additionally, the habit strength of exercise was measured by the SRHI (Verplanken &
255Orbell 2003).

256Since the measurement of the exact quantity of physical activity by self-report is limited,
257especially in children (Sallis & Saelens 2000), physical activity measurement was
258complemented objectively in a sub-sample of children by accelerometers (StepWatch
259Activity Monitor™) for 7 consecutive days before and after the intervention.

260Sedentary time was determined by a questionnaire for children concerning the time for
261television and computer use and other sedentary activities per week (Lampert *et al.* 2007b),
262Again, this evaluated questionnaire was also integrated in the German representative

263KIGGS study (Lampert *et al.* 2007b;Kurth *et al.* 2008). In addition the SRHI for watching
264TV was employed (Verplanken & Orbell 2003).

265A final secondary aim was to identify prognostic factors for the effect of the lifestyle
266intervention. Identifying which children will profit from this kind of intervention will help
267to develop tailored interventions. Socio-economic status (SES), ethnicity, and parent BMI
268are known influencing factor on the effectiveness of lifestyle interventions in obese
269children (www.a-g-a.de/Leitlinie.pdf 2011;Oude *et al.* 2009). Therefore, we measured SES
270of the family by determining the Winkler-index developed for German health surveys
271(Lange *et al.* 2007) according to the representative KIGGS study (Kurth *et al.* 2008). This
272multidimensional index considers parents' education, occupational state, and household
273income and is separated into 3 groups (low, medium and high). The higher score of mother
274and father was used per household. Children whose parents were both immigrated or of
275non-German citizenship and those who were immigrated themselves and simultaneously
276had at least one parent of non-German origin were classified as ethnic minorities. All other
277boys and girls were classified as non-migrants (Schenk *et al.* 2007). Weight and height of
278parents and siblings were self-reported by the parents and their BMI was calculated.

279Study protocol

280All variables have to be assessed at baseline and the end of intervention or waiting period.
281Since overweight is a chronic disorder all variables have to be measured not only at the end
282of intervention but also at one year follow-up after the end of intervention. To have a
283conservative estimation of the treatment effect we decided to follow an intention-to-treat
284analysis approach setting all missing values at follow-up due to drop-out back to baseline
285values.

286Sample size calculation for evaluation study

287Based on a preceding phase-II feasibility cross-over trial in 19 overweight children (at
288baseline 10.7 \pm 2.1 years, 68% female, mean BMI-SDS 1.58 \pm 0.19, mean BMI 22.6 \pm 1.8
289kg/m²) the required sample size for the RCT was estimated (Reinehr *et al.* 2010c). The 19
290overweight children in the pilot study increased their degree of overweight significantly in
291the six-months waiting period before intervention (mean increase of BMI-SDS 0.15 \pm 0.19
292and mean increase of BMI 1.1 \pm 0.9 kg/m²). In the following six-month intervention period,
293by contrast BMI-SDS (mean change -0.45 \pm 0.21) and BMI (mean change -1.7 \pm 0.9 kg/m²)
294decreased significantly ($p < 0.001$). Based on these results and to get a conservative sample
295size estimate, the mean difference was reduced by 50% and the standard deviation was

296increased by 50% yielding 0.225 as group-difference in BMI-SDS change and 0.315 for its
297standard deviation. On an $\alpha=0.05$ level, two sided tests, a control to intervention ratio
298of 1 and 80% power a sample size of 64 (32 per group) was estimated for this study.

299Ethical Approval

300The local ethics committee of the University of Bremen approved this study. Written
301informed consent is obtained from all subjects and their parents prior to study start.

302Results

303Preliminary findings of the intervention “Obeldicks light”

304Our first preliminary findings may point towards an effectiveness of the new lifestyle
305intervention “Obeldicks light” for overweight children and adolescents as well as towards
306the usefulness of our study protocol and the accurateness of our study sample estimation
307(Reinehr *et al.* 2010c): Our intervention and evaluation protocol was suitable for the
308participants of the study as demonstrated by a very low drop-out rate (3% in intervention
309and 16% in the control group). Furthermore, we have demonstrated in a previous study that
310our study population did not differ from a general population in Germany concerning
311social status or ethnicity (Finne *et al.* 2009) also supporting the generalizability of our
312results and demonstrating that all social classes were addressed by our intervention. BMI-
313SDS changes were significantly different across the control and intervention group. In the
314control group ($n=32$), BMI increased significantly, while BMI-SDS did not change
315significantly. In contrast in the intervention group ($n=34$), BMI and BMI-SDS decreased
316significantly. The success rate defined by reduction of BMI-SDS was 94% in the
317intervention group. Given the observed values of the difference and standard deviations of
318BMI-SDS change the power of this study was >0.999 at a random error level of 0.05
319(Reinehr *et al.* 2010c).

320Since the intervention was offered at two different treatment centres, which did not differ
321in the outcomes of their patients, this finding supports the generalizability of our
322intervention.

323The reduction of overweight was independent of age and gender of the children (Reinehr
324*et al.* 2010c) assuming that the materials and methods of the intervention “Obeldicks light”
325are applicable to boys and girls in the age range of 8 to 16 years.

326The achieved reduction of overweight was clinically relevant as demonstrated by a
327reduction of fat mass both in bioimpedance analyses and skinfold thickness measurements

328(Reinehr *et al.* 2010c). Additionally, waist circumference was reduced significantly only in
329the intervention group (Reinehr *et al.* 2010c). Furthermore, blood pressure decreased
330significantly in the intervention group (Reinehr *et al.* 2010c).

331A previous study suggests that the reduction of overweight achieved in our lifestyle
332intervention “Obeldicks light” seems to be caused primarily by changes of dietary patterns
333(Reinehr *et al.* 2010c): The lifestyle intervention was associated with an improvement of
334dietary patterns (significant reduction of energy (kcal/day), fat and sugar consumption) in
335the intervention but not in the control group. However, the control and intervention groups
336did not differ in their sports activities and sedentary behaviour suggesting that the
337intervention failed to decrease TV and computer consumption, which is one of the most
338important goal in lifestyle interventions of overweight children (www.a-g-
339a.de/Leitlinie.pdf 2011;Oude *et al.* 2009).

340A challenge of our study was the recruitment process in spite of using multiple advertising
341strategies such as newspaper, television, broadcasting, school events, distribution of
342leaflets, and information of family doctors (Finne *et al.* 2009). Although more than 200
343families presented for participation during the first 6 months of the recruitment period of
344the evaluation study, this process resulted primarily in the enrolment of obese children,
345indicating that in the search for overweight children, predominantly obese children felt
346addressed and the subjective need for lifestyle intervention for overweight children seems
347to be low (Finne *et al.* 2009).

348

349Conclusions

350This paper describes the development of a lifestyle intervention for overweight children as
351well as its evaluation design. Our findings will probably help to implement other lifestyle
352interventions in different regions.

353Our evaluation protocol was suitable for the participants of study as demonstrated by a
354very low drop-out rate and addressing all social classes. However, our study protocol has a
355few important potential limitations. Since physical activity training, behaviour counselling,
356and nutritional education were performed simultaneously in the intervention group, we
357cannot distinguish the impact of each of them on overweight reduction. Furthermore, the
358effects of dieting and increased physical activity probably strengthened each other. Self-
359reported data were used to measure dietary habits and physical activity and it can be
360questioned as to what extent they reflect the real habits. Underreporting is a well-known

phenomenon in overweight and obese subjects (Ebbeling *et al.* 2002). Therefore, conclusions based on self-reported data such as dietary records and questionnaires have to be drawn very cautiously. However, objective measurements such as accelerometry will help us to interpret the findings.

Reducing the treatment intensity of well-established lifestyle interventions for obese children was a simple way to develop a lifestyle intervention for overweight children. The advantages are that the methods to achieve a change of lifestyle habits are well-established as well as the therapists are familiar with the implementation (as they are already experienced in “Obeldicks” training).

The achieved reduction of overweight at the end of the lifestyle intervention “Obeldicks light” was comparable to effects of lifestyle intervention in obese children (Reinehr *et al.* 2010b; Oude *et al.* 2009). This finding seems remarkable since only 50% of the physical activity lessons as well as time- and cost-intensive individual counselling were used in “Obeldicks light” as compared to the lifestyle intervention “Obeldicks” for obese children. Furthermore, the success rate in our study was much higher as compared to these studies in obese children using much more intensive interventions suggesting that an early intervention in overweight, but not obese children is preferable.

However, for the final conclusion of an effectiveness of our new lifestyle intervention “Obeldicks light”, we have to wait for the end of the follow-up study to prove whether the achieved weight loss was sustained. Furthermore, ongoing studies analyzing the changes of quality of life will help us to verify that the achieved weight reduction is also relevant for the patients. Additionally, identification of predictive factors for success in ongoing studies will help to determine which children will have the greatest profit of this kind of intervention probably influencing our inclusion criteria.

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392Conflict of interest:

393All authors have no conflict of interest

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555Table 1: Design of the evaluation study

- 556 ● Design: Randomized controlled trial with intention-to treat analyses and
557 measurements at
 - 558 ○ baseline,
 - 559 ○ end of intervention or end of waiting period, and
 - 560 ○ 1 year after end of intervention
- 561 ● Measurements:
 - 562 ○ Primary outcome: change of BMI-SDS
 - 563 ○ Secondary outcome:
 - 564 ● change of body composition (bioimpedence analysis, skinfold
565 measurements)
 - 566 ● change of cardiovascular risk factors (waist circumference, blood
567 pressure)
 - 568 ● change of quality of life (questionnaire (Ravens-Sieberer *et al.* 2008))
 - 569 ● change of health behaviour
 - 570 ○ three-day-weighed dietary records
 - 571 ○ eating habits (questionnaire (Verplanken & Orbell
572 2003;Westenhoefer & Pudel 21989))
 - 573 ○ exercise habits (questionnaire (Verplanken & Orbell
574 2003;Lampert *et al.* 2007a;Lampert *et al.* 2007b;Bös *et al.*
575 2010))
 - 576 ○ sedentary behaviour (questionnaire (Verplanken & Orbell 2003))
 - 577 ○ accelerometer measurements
 - 578 ● predictive factors:

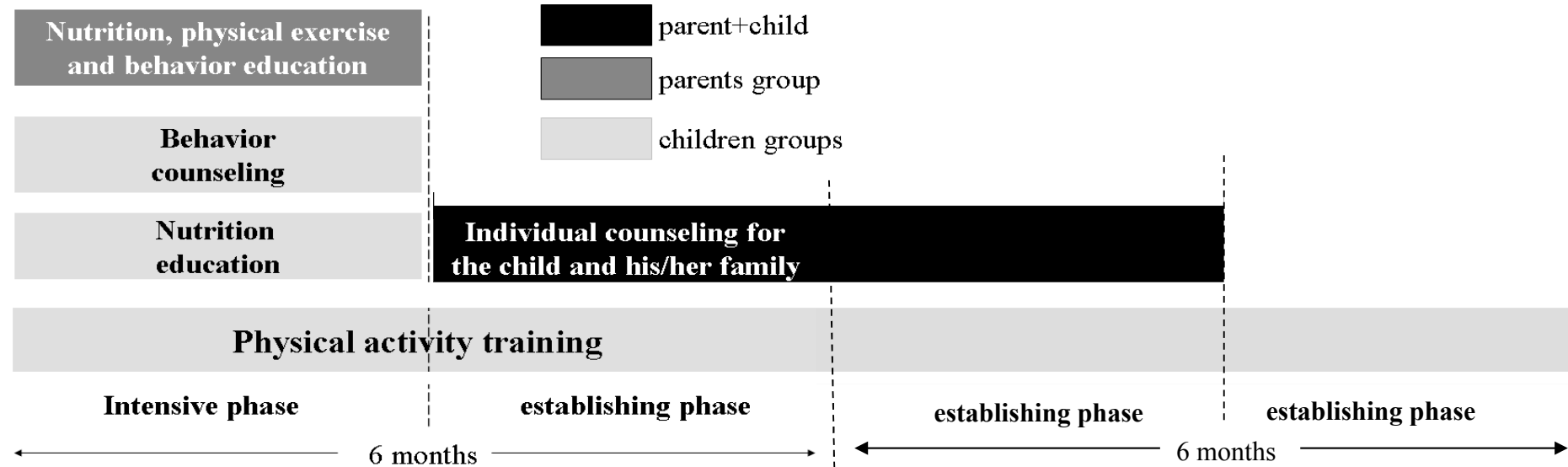
579 ○ parental BMI, ethnicity, socioeconomic status (Lange *et al.*
580 2007)

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583 Figure 1: Structure of the lifestyle intervention “Obeldicks” for obese children and
584 “Obeldicks light” for overweight children, the dashed vertical line divided the intervention
585 period into two 3-month subunits

outpatient lifestyle intervention
„Obeldicks“ for obese children



outpatient lifestyle intervention
„Obeldicks light“ for overweight children

